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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,901	01/26/2001	Joaquina Faour	PHUS-28	7749

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/770,901	Applicant(s) FAOUR ET AL.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2002 and 26 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *9 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-38, and 40-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 23, 2002 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed September 23, 2002 in Paper No. 17, and amendment and response to the Final Office Action (mailed April 9, 2002), filed September 23, 2002 in Paper No. 18 wherein the instant specification has been amended as to page 3 and 7, and claims 8, 17 and 40 have been amended; the supplemental response filed December 26, 2002. Currently, claims 1-54 are pending in this application.

As indicated in the Final Office Action (mailed April 9, 2002), "this application contains claims 9 and 39 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01." There is no cancellation of claims 9 and 39 in Applicant's response filed September 23, 2002 in Paper No. 18.

Claims 1-8, 10-38, and 40-54 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 10, 13-14, and 18-38 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular COX-II inhibitors and the particular muscle relaxants disclosed in the specification (i.e., claims 40 and 49) in composition herein, does not reasonably provide enablement for the employment any COX-II inhibitors and any muscle relaxants recited in the claims herein.

These recitations, "a COX-II inhibitor" and "a muscle relaxant", are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a composition for boosting the libido of an individual.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the broadest claim (i.e., claims 1 and 10) reads on any COX-II inhibitor and any muscle relaxant employed in the composition herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphasis added).

In the instant case, the phrase "a COX-II inhibitor" and "a muscle relaxant" in claims herein, recited in the instant claims are purely functional distinction. Hence, these

functional recitations read on any compounds that might have the recited functions. However, the specification merely provides particular COX-II inhibitors and particular muscle relaxants for the composition in claims 40 and 49.

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co*. Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art is unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host the ***combination*** of any compounds represented by "a COX-II inhibitor" and "a muscle relaxant", which might encompass more than a hundred compounds. See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible

drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art is unable to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional properties in the pharmaceutical compositions herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only one particular compound for each kind of functional compounds employed in the composition herein is disclosed in the specification. Moreover, it is noted that the specification fails to provide working examples, i.e., testing results or data to demonstrate the instant compositions (different combinations of the claimed compounds) to be administered to a host.

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be administered to a host, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-8, 12, 14, 16-18, 22-23, 28-29, 31-37, 43-45 and 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, of record in the previous Office Actions dated April 9, 2002 and September 28, 2001.

The expressions "slow or rapid release", for example, in claim 12, “rapidly”, for example, in claim 18, “rapid, immediate.. slow, timed, target, pseudo-first order,

.....second order and/or delayed release..", for example, in claim 29, and "rapid release" or "a delayed but rapid release" in claims 31-37, renders claims 7-8, 12, 14, 16-18, 22-23, 28-29, 31-37, 43-45 and 52-54 indefinite. The expressions "slow or rapid release", "rapidly", "rapid, immediate.. slow, timed, target, pseudo-first order, ...second order and/or delayed release..", and "rapid release" or "a delayed but rapid release" are not defined by the claims. Therefore, the scope of claims is indefinite as to how slow or rapid release may be considered "slow or rapid release", "rapidly", "rapid, immediate.. slow, timed, target, pseudo-first order, ...second order and/or delayed release..", and "rapid release" or "a delayed but rapid release".

Applicant's remarks and Attachments A-D filed on September 23, 2002 in Paper No. 18 with respect to this rejection have been fully considered but they are not deemed persuasive to remove the rejection. As discussed in the previous Office, these expressions are considered indefinite since they are relative terms. Note that the instant claims are not limited to the drug release profiles in the examples herein in the specification. Moreover, the definitions or explanations for "slow or rapid release", "rapidly", "rapid, immediate.. slow, timed, target, pseudo-first order, ...second order and/or delayed release..", and "rapid release" or "a delayed but rapid release" in Attachments A-D are unclear as to what is the distinction between these different drug releases.

Claims 7-8, 16-17, and 40-48 are rejected for reasons stated in the previous Office Actions dated April 9, 2002 and September 28, 2001, containing the trademark/trade name, e.g., SC-5766, SC-58215, and T-614. Where a trademark or

trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular active agents herein and, accordingly, the identification/description is indefinite.

Applicants are suggested to replace these names with real chemical names and provide the support for the identification for these names.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-38, and 40-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch et al. (WO 99/13799, of record) in view of Okada et al. (5,476,663, PTO-892).

Burch et al. discloses that COX-II inhibitors such as rofecoxib (VIOXX or MK-966) are known to be useful in a composition and a method of treating pain. Burch et al. discloses that the composition therein comprising a COX-II inhibitor can also be combined with other active agents, e.g., other analgesic agents, or pharmaceutical expcipients, e.g., colorant and flavorant. Burch et al. further discloses various dosage forms, e.g., tablet, capsules and gelcaps that may control release of the active ingredients therein. See title and abstract, page 5 lines 7-8, page 13 lines 25-27, page 14 lines 4 and 23-30, page 23 and claim 10.

The prior art does not expressly disclose that the employment of the particular COX-II inhibitor such as rofecoxib in combination with the particular muscle relaxant such as pridinol in a pharmaceutical composition or dosage. The prior art does also not expressly disclose the effective amounts of active agents in the composition herein to be administered, e.g., the weight ratio of the COX-II inhibitor and the muscle relaxant.

Okada et al. teaches that a muscle relaxant such as pridinol is useful in combination with analgesic and/or antiinfammatory drugs (see col.3 lines 13-28).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a COX-II inhibitor such as rofecoxib in combination with a muscle relaxant such as pridinol in a pharmaceutical composition or dosage, and to optimize the effective amounts of active agents in the composition herein to be administered, e.g., the weight ratio of a COX-II inhibitor and a muscle relaxant.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a COX-II inhibitor such as rofecoxib in combination with

a muscle relaxant such as pridinol in a pharmaceutical composition or dosage since COX-II inhibitors such as rofecoxib are known to be useful in a composition or dosage and a method of treating pain. Moreover, muscle relaxants such as pridinol are well known to be useful alone or in combination with conventional analgesics for the treatment of pain. Therefore, one of ordinary skill in the art would have reasonably expected that combining a COX-II inhibitor such as rofecoxib and a muscle relaxant such as pridinol known useful for the same purpose in a composition to be administered would improve the therapeutic effect for treating pain. Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of known amounts of known active agents to be administered is considered well within the skill of artisan.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Since all active composition components herein are known to useful to treat pain, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on January 24, 2002 in Paper No. 10 and the supplemental declaration of Ethel C. Feleder under 37 C.F.R. 1.132 filed on September 23, 2002 in Paper No. 19 with respect to this rejection of claims 1-8, 10-38, and 40-54 made under 35 U.S.C. 103(a) over Burch et al. have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicants assert that in the supplemental declaration of Ethel C. Feleder under 37 C.F.R. 1.132 filed on September 23, 2002, "The data demonstrate that the combination of rofecoxib (a COX-II inhibitor) and pridinol (a muscle relaxant) unexpectedly provides an improvement over the closest prior art. Moreover, unlike the prior art, the claimed combination can provide a synergistic analgesic effect..". However, there is no factual data in the testing results for the claimed combination herein, but mere three unsupported conclusions (see the declaration at page 3, "The following results were obtained"). Thus, the supplemental declaration of Ethel C. Feleder is insufficient to establish the fact that the claimed combination has any unexpected synergism because the declaration lacks any factual evidence for the synergism produced by the instant combination. Again, the examiner agrees with Dr. Feleder that the discovery or expectation of a synergistic analgesic effect from a combination of analgesic drugs or drug classes is unpredictable. Nevertheless, the record contains no clear and convincing evidence of unexpected results or unexpected synergistic analgesic effect produced by the combination herein over the prior art. Therefore, the declaration is insufficient to rebut the prima facie case herein.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 17, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

4/20/03